3732

PTO/SB/21 (09-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
be Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/940545
Filing Date	August 29, 2001
First Named Inventor	Lloyd Wolfinbarger, Jr., et al.
Art Unit	3732
Examiner Name	David Comstock
Attorney Docket Number	64230-00005USD2

ENCLOSURES (Check all that apply) Fee Transmittal Form Drawing(s) Fee Attached Licensing-related Papers Amendment/Reply After Allowance Communication to TC Appeal Communication to Board of Appeals and Interferences Amendment/Reply After Final Petition to Convert to a Provisional Application Affidavits/declaration(s) Extension of Time Request Extension of Time Request Terminal Disclaimer Express Abandonment Request Terminal Disclaimer Coertified Copy of Priority Document(s) Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under Reply to Missing Parts under Signature Signature Firm Name Signature Printed name W Jackson Matney, Jr. Reg. No. 39,292		-l	
Fee Attached	EN	ICLOSURES (Check all that app	oly)
Appeals and Interferences Appeals and Interferences Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) After Final After Final After Final After Final After Final After Final Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Address Extension of Time Request Terminal Disclaimer Express Abandonment Request X Information Disclosure Statement CD, Number of CD(s) Reply to Missing Parts/Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 Reply to Missing Parts under 37 CFR 1.52 or 1.53 Appeals and Interferences Appeals and Interferences Appeals and Interferences Appeals and Interferences Appeal Sand Interferences Appeal Sommetice Interferences Appeal Sand Interferences Provisional Application Provisional Application Provisional Application Provisional Application Provisional Application Provisional Appeal Sand Interferences Prov	Fee Transmittal Form	Drawing(s)	
After Final After Final After Final Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Address Extension of Time Request Express Abandonment Request Information Disclosure Statement CD, Number of CD(s) Reply to Missing Parts/Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name Signature Printed name After Final Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence Address X Other Enclosure(s) (please Identify below): Return Receipt Postcard Return Receipt Postcard FEB 2 8 2005 TECHNOLOGY CENTER Fi3700	Fee Attached	Licensing-related Papers	
Affidavits/declaration(s) Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Reply to Missing Parts / Incomplete Application Reply to Missing Parts under SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name Signature Provisional Application Power of Attorney, Revocation Change of Correspondence Address Incomplete Application Request for Refund CD, Number of CD(s) Remarks Remarks Remarks Remarks Remarks RECEIVED Remarks TECHNOLOGY CENTER #3700	Amendment/Reply	Petition	
Extension of Time Request Express Abandonment Request Information Disclosure Statement Certified Copy of Priority Document(s) Reply to Missing Parts Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name Signature Signature Change of Correspondence Address X Other Enclosure(s) (please Included in the Incompleted Address) Request for Refund Request for Refund Request for Refund Request for Refund Return Receipt Postcard Return Receipt Postcard Return Receipt Postcard Return Receipt Postcard Firm Name Signature Signature Printed name W Jackson Matney, Jr.	After Final	1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	Proprietary Information
Express Abandonment Request Request for Refund Return Receipt Postcard	Affidavits/declaration(s)		Status Letter
X Information Disclosure Statement	Extension of Time Request	Terminal Disclaimer	
Certified Copy of Priority Document(s) Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name Signature Printed name W Jackson Matney, Jr. Page No. Landscape Table on CD RECEIVED Remarks Remarks FEB 2 8 2005 TECHNOLOGY CENTER Fla700	Express Abandonment Request	Request for Refund	Return Receipt Postcard
Reply to Missing Parts/ Incomplete Application Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name Signature Signature Printed name W Jackson Matney, Jr. Remarks	x Information Disclosure Statement	CD, Number of CD(s)	
Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name JENKENS & GILCHRIST. A PROFESSIONAL CORPORATION Signature Printed name W. Jackson Matney, Jr.		Landscape Table on CD	DECENTER.
Reply to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name JENKENS & GILCHRIST. A PROFESSIONAL CORPORATION Signature Printed name W. Jackson Matney, Jr.	Reply to Missing Parts/	Remarks	HEOFINED -
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name JENKENS & GILCHRIST. A PROFESSIONAL CORPORATION Signature Printed name W. Jackson Matney, Jr.		·	
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Name JENNENS & GILCHRIST. A PROFESSIONAL CORPORATION Signature Printed name W. Jackson Matney, Jr.			TECHNOLOGY CENTER FI3700
Signature Printed name W. Jackson Matney, Jr. Page No.			
Signature Printed name W. Jackson Matney, Jr. Page No.	SIGNAT	URE OF APPLICANT, ATTORNEY, OF	R AGENT
Printed name W. Jackson Matney, Jr. Page No. 1		RIST A PROFESSIONAL CORPO	RATION
W. Jadkson Matney, Jr.	Signature Wull or	$(A, \rightarrow (),$	
Date February 15, 2005 Reg. No. 39,292	Printed name W Jackson Matney	, Jr.	
	Date February 15, 2005	Reg. No.	39,292



Docket No.: 64230-00005USD2

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Lloyd Wolfinbarger, Jr., et al.

Application No.: 09/940545

Confirmation No.: 5273

Filed: August 29, 2001

Art Unit: 3732

For:

PLASTICIZED BONE AND SOFT TISSUE

GRAFTS AND METHODS OF MAKING

AND USING SAME

Examiner: David Comstock

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

RECEIVED

FEB 2 8 2005

Dear Sir:

TECHNOLOGY CENTER R3700

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

A copy of each of the non-patent references on the PTO/SB/08 is attached.

02/22/2005 HDEMESS1 00000005 09940545

01 FC:1806

180.00 OP

Application No.: 09/940545 Docket No.: 64230-00005USD2

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Our check in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p) is enclosed. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 10-0447, under Order No. 64230-00005USD2. A duplicate copy of this paper is enclosed.

Dated: February 15, 2005

Respectfully submitted,

W. Jackson Matney, Jr.

Registration No.: 39,292

JENKENS & GILCHRIST, A PROFESSIONAL

CORPORATION

901 15th Street, Suite 900

Washington, DC 20005

(202) 326-1500

Attorneys For Applicant

Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 3

	IN LIEU OF PTO-3B/08	
Complete if Known		
Application Number	09/940545	
Filing Date	August 29, 2001	
First Named Inventor	Lloyd Wolfinbarger, Jr., et al.	
Art Unit	3732	
Examiner Name	David Comstock	
Attorney Docket Number	64230-00005USD2	

		1	U.S. PA	TENT DOCUMENTS
Examiner	Cite	Document Number	Publication Date	Name of Patentee or
itials*	No.	Number-Kind Code ² (if known)		Applicant of Cited Document
	1	US-4539716	09/1985	Bell
	2	US-4546500	10/1985	Bell
	3	US-4776853	10/1988	Klemet, et al.
	4	US-4801299	01/1989	Brendel, et al.
	5	US-4835102	05/1989	Bell, et al.
	6	US-4846835	07/1989	Grande
	7	US-4969912	11/1990	Kelman, et al.
	8	US-5171273	12/1992	Silver, et al.
	9	US-5352463	10/1994	Badylak, et al.
	10	US-5432712	07/1995	Chan
	11	US-5525646	06/1996	Lundgren, et al.
	12	US-5556379	09/1996	Wolfinbarger, Jr.
	13	US-5558875	09/1996	Wang
	14	US-5607476	03/1997	Lundgren, et al. Wolfinbarger, Jr. Wang Prewett, et al. Goldstein Goldstein Cavallaro
	15	US-5613982	03/1997	Goldstein For B 2 8 200
	16	US-5632778	05/1997	Goldstein CHNO
	17	US-5718012	02/1998	
	18	US-5792603	08/1998	Dunkelman, et al.
	19	US-5797871	08/1998	Wolfinbarger, Jr.
	20	US-5820581	10/1998	TVOIIII baiger, 31.
	21	US-5843180	12/1998	Jaffe, et al.
	22	US-5843181	12/1998	Jaffe, et al.
	23	US-5843182	12/1998	Goldstein
	24	US-5855617	01/1999	Orton
	25	US-5855620	01/1999	Bisphoric, et al.
	26	US-5863531	01/1999	Naughten, et al.
	27	US-5885617	01/1999	Orton
	28	US-5899936	05/1999	Goldstein
	29	US-5916266	06/1999	Yui, et al.
	30	US-5928945	07/1999	Seliktar
	31	US-5944755	08/1999	Stone
	32	US-5976104	11/1999	Wolfinbarger, Jr.
	33	US-5977034	11/1999	Wolfinbarger, Jr.
	34	US-5977432	11/1999	Wolfinbarger, Jr., et al.
	35	US-5993844	11/1999	Abraham, et al.
	36	US-5997896	12/1999	Carr, Jr., et al.
	37	US-6024735	02/2000	Wolfinbarger, Jr.
	38	US-6110206	08/2000	Stone
	39	US-6162258	12/2000	Scarborough, et al.
	40	US-6200347	03/2001	Anderson, et al.
	41	US-6277555	08/2001	Duran, et al.
	42	US-6293970	09/2001	Wolfinbarger, Jr.
	43	US-6294041	09/2001	Boyce et al.
	44	US-6312474	11/2001	Francis, et al.
	45	US-6352708	03/2002	Duran, et al.
	46	US-6371992	04/2002	Tanagho, et al.
	47	US-6376244	04/2002	Atala

Examiner Date Signature Considered

Complete if Known Substitute for form 1449A/B/PTO Application Number 09/940545 INFORMATION DISCLOSURE Filing Date August 29, 2001 STATEMENT BY APPLICANT First Named Inventor Lloyd Wolfinbarger, Jr., et al. Art Unit 3732 (Use as many sheets as necessary) Examiner Name **David Comstock** 64230-00005USD2 Sheet 2 of 3 Attorney Docket Number

48	US-6416995	07/2002	Wolfinbarger, Jr.
49	US-6428802	08/2002	Atala
50	US-6432710	08/2002	Boss, Jr., et al.
51	US-6432712	08/2002	Wolfinbarger, Jr.
52	US-6448076	09/2002	Dennis, et al.
53	US-6458158	10/2002	Anderson, et al.
54	US-6479064	11/2002	Atala
55	US-6544289	04/2003	Wolfinbarger, Jr., et al.
56	US-6569200	05/2003	Wolfinbarger, Jr., et al.
57	US-6630001	10/2003	Duran, et al.
58	US-6734018	05/2004	Duran, et al. Wolfinbarger, Jr.
59	US-6743574	06/2004	Wolfinbarger, Jr. Wolfinbarger, Jr. Gabay Duran, et al. Wolfinbarger, Jr., et al. Wolfinbarger, Jr. et al.
60	US-6783556	08/2004	Gabay
61	US-2001/0004715	06/2001	Duran, et al.
62	US-2003/0083752	05/2003	Wolfinbarger, Jr., et al.
63	US-2003/0087428	05/2003	Wolfinbarger, Jr., et al.
64	US-2003/0135284	07/2003	Crouch, et al.
65	US-2003/0217415	11/2003	Crouch, et al.
66	US-2004/0057936	03/2004	Cheung, et al.
67	US-09/698493		Anderson, et al.

	FOREIGN PATENT DOCUMENTS				
Examiner	Cite	Foreign Patent Document	Publication	Name of Patentee or	
Initials*	No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Date MM-DD-YYYY	Applicant of Cited Document	™

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	68	Wolfinbarger, L., Zhang, YI, Adam, BLT., Hornsi, D., Gates, K., and Sutherland, V., 1994, "Biomechanical aspects on rehydrated freeze-dried human allograft dura mater tissues" J. Applied biomaterials, 5:265-270.	
	69	HH. Sievers, et al., "Decellularized pulmonary homograft for reconstruction of the right ventricular outflow tract: first clinical experience" Z. Kardiol, Vol. 92, No. 53, 2003.	
	70	Robert Madden, et al., "Decellularized Cadaver Vein Allografts Used for Hemodialysis Access Do Not Cause Allosensitization or Preclude Kidney Transplantation" Journal of Kidney Diseases, Vol. 40, No. 6, 2002, 1240-1243.	
	71	P.M. Dohmen, et al., "In Vitro hydrodynamics of a decellularized pulmonary porcine valve, compared with a glutaraldehyde and polyurethane heart valve" Journal of Artificial Organs, Vol. 25, No. 11, 2002, 1089-1094.	
	72	B.S. Conklin, et al., "Development and evaluation of a novel decellularized vascular xenograft" Medical Engineering and Physics, Vol. 24, 2002, 173-183.	

Examiner	Date
Lizammer	Date
Signature	Canaidored
Signature	Considered



FEB 2 8 2005

TECHNOLOGY CENTER R3700

3

IN LIEU OF PTO-SB/08.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of

Ose as many sneets as necessary

3

Sheet

Complete if Known		
Application Number	Application Number 09/940545	
Filing Date August 29, 2001		
First Named Inventor	Lloyd Wolfinbarger, Jr., et al.	
Art Unit	3732	
Examiner Name	David Comstock	
Attorney Docket Number	64230-00005USD2	

73	J. Clark, et al., "Decellularized Dermal Grafting in Cleft Palate Repair" Facial Plastic Surg., Vol. 5, 2003, 40-44.	
74	Ronald C. Elkins, et al., "Decellularized Human Valve Allografts" Society of Thoracic Surgeons, 2001, S428-432.	
75	Steven Goldstein, et al., "Transpecies Heart Valve Transplant: Advanced Studies of a Bioengineered Xeno-Autograft" Society of Thoracic Surgeons, 2000, 1963-1969.	
76	Pascal M. Dohmen, et al., "Ross Operation with a Tissue-Engineered Heart Valve" Society of Thoracic Surgeons, 2002, 1438-1442.	
77	David W. Courtman, et al., "Biomechanical and ultrastructural comparison of cryopreservation and a novel cellular extraction of porcine aortic valve leaflets" Journal of Biomedical Materials Research, Vol. 29, 1995, 1507-1516.	
78	Gregory Wilson, et al., "Acellular Matrix Allograft Small Caliber Vascular Prostheses" Trans. Am. Sog. Artif. Intern. Organs, 1990, Vol. XXXVI, M340-343	
79	David W. Courtman, et al., "The Acellular Matrix Vascular Prosthesis: Investigation of its Potential as a Xenograft for Clinical Application" Biomaterial Tissue Interfaces, Vol. 10, 1992, 241-246.	
80	David W. Courtman, et al., "Development of a pericardial acellular matrix biomaterial: Biochemical and mechanical effects of cell extraction" Journal of Biomedical Materials Research, Vol. 28, 1994, 655-666.	
81	Gregory J. Wilson, et al., "Acellular Matrix: A Biomaterials Approach for Coronary Artery Bypass and Heart Valve Replacement" Society of Thoracic Surgeons, 1995, S353-358.	
82	Sotiris A. Korrossis, et al., "Tissue Engineering of Cardiac Valve Prostheses II: Biomechanical Characterization of Decellularized Porcine Aortic Heart Valves" Heart Valve Disease 11, 2002, 463-471.	
83	Schwade, N., "Implants, Soft Tissue, Alloderm," emedicine.com, copyright 2004	
84	Kreuz, F., et al., "The Preservation and Clinical Use of Freeze Dried Bone," J Bone Joint Surg. 1951; 33A: 863	
85	Lalka, et al., "Acellular vascular matrix: A natural endothelial cell substrate," Annals of Vascular Surgery, Vol. 3, No. 2, 1989, 108-117.	
86	Boyne, P., Cryobiology, Vol. 4, No. 6 (1968), pages 341-357.	
87	Pappas, A., Cryobiology, Vol. 4, No. 6 (1968), pages 358-375	
88	Triantafyllou et al., Acta Orthopaedica Belgica, Vol. 41, Suppl. I, (1975), pages 35-44.	
89	Pelker, et al., Clinical Orthopaedics and Related Research, No. 174, (April 1983), pages 54-57.	
90	Pelker, et al., Journal of Orthopaedic Research, Vol. 1, No. 4, (1984), Pages 405-411.	
91	Pelker, et al., Orthopedic Clinics of North America, Vol. 18, No. 2, (April 1987), pages 235-239.	
92	Jerosch et al., Zeitschrift Orthopadie 132, (1994), pages 335-341.	
93	Voggenreiter et al., Archives of Orthopaedic and Traumatic Surgery, Vol. 113, (1994), pages 294-296	
94	Kang et al., Yonsei Medical Journal, Vol. 36, No. 4, (1995), pages 332-335.	
95	Bianchi et al., 21 st Annual Meeting, American Association of Tissue Banks, (August 23-27, 1997), page 48.	
96	Balderson et al., 45 th Annual Meeting, Orthopaedic Research Society, (February 1-4, 1999), pages 785.	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner	Date
Signature	Considered

^{&#}x27;Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.